NCAD DUBLIN
National College of Art and Design
A Recognised College of University College Dublin

Human Factors II
PGDES1006

MODULE DESCRIPTOR

ECTS credits[1]	5	**Programme**	MSc Medical Device Design
NQF level	9	**School**	School of Design
Stage	1	**Module Co-ordinator**	Enda O'Dowd
Trimester	Spring	**Module Team**	Enda O'Dowd, Derek Vallence, Paul Fortune,
Contact	Enda O'Dowd odowde@staff.ncad.ie		
Responsibility	The NCAD Academic Council, and the School of Design have responsibility for this module.		

1. Introduction

This module builds on the knowledge and skills gained in the Human Factors I module. Along with an introduction to biomechanics, the students will be introduced to risk management and design controls in accordance with industry standards. It equips the students with bottom up and top down approaches to human factors evaluation and testing in accordance with international standards. The module is taught as a series of lectures and workshops. Along with the exercises which will be directly assessed in this module many of the methods will be applied in the following modules: Collaborative Project 2, Collaborative Project 3 and Major Thesis Project.

Human factors evaluation is an important component of risk management in the design and development of medical devices.

The aims of this module are to:

- Introduce students to risk management in the design and development of medical devices and the relevant standards which apply.
- Provide students with the tools to evaluate medical devices from a user perspective.
- Provide the skills needed to be the user advocate on a medical device design team.
- Develop graduates who can be user-centred design advocates on a medical device design team.
- Provide students with a thorough understanding of biomechanics as applied in the context of medical device design.
- Instil the need to evaluate, test and document user needs throughout the design and development process.

2. What will I learn?

On successful completion of this module students will be able to:

[1] European Credit Transfer and Accumulation System, where 60 ECTS credits equate to the workload of a full-time academic year

1. Analyse the use of a medical device using both top down and bottom up risk analysis approaches.
2. Define the uses, intended users and intended use environments for a medical device.
3. Identify known or foreseeable hazards in the use of a medical device.
4. Translate customer needs into design inputs and outputs.
5. Plan a formative usability study in order to identify usability problems with a design during the development cycle.
6. Document a formative usability testing protocol.
7. Describe in detail a complex biomechanical system.
8. Present a complex biomechanical concept in an accessible and engaging format.

Module content

Lecture content will be delivered on various human factors topics with an emphasis on evaluative methods in order to provide a critique on existing devices and early stage prototypes. Workshops will be facilitated in order to introduce students to the various approaches to medical device evaluation from a user perspective. These workshops will include Fault Tree Analysis, Failure Modes and Effects Analysis (FMEA) and Traceability Matrix development.

A series of lectures are delivered on various aspects of biomechanical systems in the body. These are delivered by visiting lecturers from the bioengineering departments in Trinity College Dublin (TCD) and University College Dublin (UCD).

3. How will I learn?

This module will be taught through a combination of lecture content, practical workshops and studio practice. You will learn to work independently and as part of a team to replicate industry practice. You will learn to evaluate existing medical devices and your own concepts produced through your collaborative project work. You will learn to document the process of device evaluation to international industry standards.

Learning tool	Hours
Lectures and seminars	24 hours
Specified Learning Activities	18 hours
Autonomous Student Learning	58 hours
Total Workload	**100**

4. What learning supports are provided?

Learning will be supported through lectures, lecture notes, seminars, suggested readings appropriate to your discipline, tutorial and field-trips as appropriate. A number of guest lectures and workshops will be delivered by industry professionals and regulatory bodies as part of this module.

Recommended text books for this module will be available from the NCAD Library.

- Association for the Advancement of Medical Instrumentation, 2010. *Human factors engineering – Design of medical devices.* Arlington, VA: Association for the Advancement of Medical Instrumentation.
- Michael Wiklund, A. D. E. D., 2016. *Medical Device Use Error - Root Cause Analysis.* 1st ed. New York : CRC Press .
- Privitera, M. B., 2019. *Applied Human Factors in Medical Device Design.* 1st ed. London: Elsevier.

5. Am I eligible to take this module?

Module Requisites and Incompatibles	
Pre-requisites	Human Factors I
Co-requisites	Design Studio Collaborative Project 1 and 2
Incompatibles	*None*.
Prior learning	Where a student can demonstrate that they have achieved at least 80% of the learning outcomes of this module, by academic certified achievement, or through quantifiable and documented experience, they can apply to the School for that prior learning to be recognised. Applications must be received prior to the commencement of delivery of the module.
Recommended	*None*.

6. How will I be assessed?

Assessment tool	% of final grade	Timing
Device Risk Analysis	30%	End of Trimester 2
Traceability Matrix	10%	End of Trimester 2
Formative Testing Protocol	30%	End of Trimester 2
Biomechanics poster	30%	End of Trimester 2
Total	**100%**	

The Device Risk Analysis, Traceability Matrix and Formative Testing Protocol will be based on workshop exercises carried out in the medical device design studio. Where possible these exercises will be conducted on devices related to the collaborative studio project work. The Biomechanics poster assignment is an opportunity to translate the complex biomechanical concepts introduced in lectures to an accessible visual format.

Assessment tool	**Learning outcomes assessed**
Device Risk Analysis	1, 2 and 3
Traceability Matrix	4
Formative Testing Protocol	5 and 6
Biomechanics poster	7 and 8

7. Feedback, results and grading

This module will be graded in accordance with the standard NCAD grading criteria and will contribute to the overall programme award of PGDip/MSc Medical Device Design.

8. What happens if I fail?

Resit Opportunities

Opportunities will be provided during or at the end of Trimester 3 to students who do not complete all assessments in Trimester 2, but students will not be able to progress to the next stage of the programme until they have successfully completed all Trimester 1 and 2 modules, equivalent to 60 credits.

9. When and where is this module offered?

Medical Device Design Studio

Seminar room

Online

Spring Trimester (January to May)

10. How will I have the chance to evaluate the module?

It is important to NCAD that students inform the development of teaching and learning at NCAD. We encourage all students to communicate their concerns and their observations about their study to members of staff so that any changes can be made in a timely manner.

About two-thirds of the way through the year, a student forum will be convened to gather students' comments about their study and the delivery of the programme. In addition, at the end of Trimester 2, students have the opportunity to complete an online evaluation of their study and experience at NCAD. These evaluation events are important to current and future students, to ensure we can enhance the delivery of programmes at NCAD.

In addition, you are invited to discuss your experience on the module with your lecturers at any point during the year. You can also relay your comments to the class student representative who will communicate your comments to the staff.

For further details on the content of your module and teaching arrangements, consult your Programme or Module Handbook